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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/935,717 04/17/98 1641

90 04/17/98

EXAMINER

HMC32/C-317

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ART UNIT

PAPER NUMBER

2

1641

DATE MAILED:

04/17/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 9/23/97

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-10 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. This application has been filed with drawings which are acceptable for examination and have not been objected to by the draftsman.

3. ***Claim Rejections - 35 U.S.C. § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3 recite the phrase "or the like"; it is not clear what other types of carrier strips are being claimed. Clarification is requested.

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Claims 1 and 3, and the claims dependent therefrom recite the phrase 'lock and key'; the full meaning of this phrase is not clearly set forth as the phrase appearing in quotes could mean more than recited. Clarification is requested.

Claim 7 and the claims dependent there from recite the phrase " 'snap' engagement"; the full meaning of this phrase is not clearly set forth as the phrase appearing in quotes could mean more than recited. Clarification is requested.

It is understood by the examiner that the claims which recite the word "means" are claiming only those embodiments which are specifically recited in the specification of the instant specification and are therefore narrowly defined as only those embodiments which are specifically recited.

6. *Claim Rejections - 35 U.S.C. § 102*

7. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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8. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative obvious over Catt et al WO 95/13531.

Catt et al disclose a reading device for test strips, wherein the test strips are claimed in combination with a test strip reader, as well as claims the combination in a form of a kit. The

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assay test strip may comprise the use a particulate direct label or the use of a label which is detected through the use of electromagnetic radiation. The relationship of the test strip and the reading device is one in which the spacial relationship is interlocking to insure that a predetermined spacial relationship relative to said reading means is maintained. When the device is received into the reading device the receiving means includes an actuating means which is triggered (claim 13) by the receipt of the device and the actuating means causing the reading of the detection zone to be initiated. The test kits may comprise one or a plurality of the assay devices (claim 22) for the determination of an analyte. Catt et al differs from the instantly claimed invention by failing to show the detection of more than one analyte.

9. Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to determine more than one analyte with the test kits of Catt et al because Catt et al discloses that the combination test kits may comprise more than one assay device and Catt et al teaches that “[T]he invention can be used in the determination of any body fluid analyte, especially in the monitoring of the human ovulation cycle by the determination of one or more hormones or metabolites thereof in body fluid, such as urine for example either LH and/or estrone-3-glucuronide. (page 12, lines 4-8)” There the person of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in obtaining test kits which would be able to determine one or more analytes in a sample of fluid because Catt et al teach that these analytes are important in the determination of the ovulation cycle and would aid

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in the identifying the time in which fertility was greatest based on the assessment of more than one hormone level.

10.

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al (US Pat. 5,526,120, filing date September 8, 1994).

Jina disclose a test strip with an asymmetrical end which insures the correct insertion for measuring for an analyte in a liquid sample. The asymmetries combine to permit a test strip to be inserted into the apparatus when it is correctly aligned and is associated with circuitry when the

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strip is fully inserted. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures) Jina teach that the device is useful in the determination of glucose, cholesterol and alcohol in human blood (col. 5, line 35). Jina differs from the instantly claimed invention by failing to show the formulation of the assay test strip and apparatus into kit form for the determination of one or more analytes.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to determine one or more one analytes with the device of Jina because Jina discloses that the device is useful in the determination of more than one analyte and the person of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in obtaining test kits which would be able to determine one or more analytes in a sample of fluid because Jina teach devices and means for the evaluation of analytes and kits are an art recognized means for the convenient distribution of assay components to the desired end user for the determination of biologically significant analytes.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
15. **Pearson et al (DES. 379,662)** is cited to show a combined testing instrument and cap.
16. **Pearson et al (DES.379,663)** is cited to show a testing instrument.

17. **Pearson et al (DES. 380,837)** is cited to show a pregnancy test result reader.
18. **Phillips et al (US Pat. 5,059,394)** is cited to show an analytical device for the automatic determination of analytes in fluids, wherein an timing circuit is triggered by an initial decrease in reflectance by the wetting of the surface whose reflectance is being measured as it passes through the inert matrix.
19. **Catt et al (US Pat. 5,467,778 and EP 0703 454 a1)** are cited to show a monitoring method for the status of a current ovulation cycle of an individual human female subject.
20. **Clark (US Pat. 5,726,010)** is cited to show a reversible flow chromatographic binding assay for the detection of an analyte in a fluid sample.
21. **de Zoeten et al (US Pat. 5,611,995)** is cited to show an apparatus for the detection of a specifically reacting substance which utilizes a transport for a liquid by capillary forces and an indicator system for the presence or absence of the substance to be detected.
22. **May et al (US Pat. 5,656,503 and 5,602,040)** are cited to show test devices for detecting analytes in biological samples.
23. **Moorman et al (US Pat. 5,356,782)** is cited to show an analytical test apparatus with a negative and positive control and is used for the determining of an analyte.
24. **Senior (US Pat. 5,504,013 and EP 653 639 A1)** are cited to show analytical devices and methods of use for the determining of an analyte in a liquid sample.
25. **Smith et al (US Pat. 5,108,889)** is cited to show an assay for determining an analyte using mercury release followed by detection via interaction with aluminum.

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26. **Yang et al (US Pat. 5,354,692)** is cited to show an analyte detection device including a hydrophobic barrier for improved fluid flow.

27.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 305-7939.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
April 7, 1998

James C. Housel
JAMES C. HOUSEL 4/13/98
SUPERVISORY PATENT EXAMINER